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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/662,877 | 09/16/2003 | Richard J. Whitbourne | 32286-191984 | 1150 |
| 26694 | 7590 | 02/28/2006 | EXAMINER | |
| VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998 | | | HO, UYEN T | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |
| DATE MAILED: 02/28/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,877

Applicant(s)

WHITBOURNE ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/13/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species 5, subspecies 1 in the reply filed on 12/13/2005 is acknowledged. The traversal is on the ground(s) that species are not mutually exclusive. This is found persuasive therefore, restriction requirement of the previous office action (mailed 10/19/05) is withdrawn. Since species/restricted inventions are not mutually exclusive, one species/invention unpatentable over a prior art, the prior art will be used in a rejection under 35 U.S.C. 103 (a) of the other species/inventions.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the limitation "the drug release layer" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-26, 28-35, 39, 47, 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Pacetti et al. (6,663,662).

Regarding claims 1-2, 47 and 49-52, Pacetti et al. disclose a primer layer/anchor polymer comprising one or more polymers (col. 4, line 38 to col. 8, lines 42), a drug reservoir layer comprising an intermediate layer (34) and a drug release layer (28) that have one or more polymers and one or more active agent (col. 4, line 45 to col. 15, line 46).

Regarding claim 3, the particles being made from materials (col. 14, lines 15-36) that is capable of enhancing visibility.

Regarding claim 4, the primer layer is a single layer (32).

Regarding claims 5-7, 12, 13, 29, 39-41, the anchoring polymers as claimed (col. 4, lines 38 to col. 8, lines 42).

Regarding claims 8-11, 14-20, 30-35, 42- the drug reservoir layer comprising the material as claimed (col. 4, lines 45 to col. 15, line 46).

Regarding claims 21-23, the thickness as claimed for each layer (col. 18, line 50, to col. 19, lines 12).

Regarding claims 25-26, the active agent as claimed (col. 11).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 27, 36-38, 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. '662. Pacetti et al. disclose all the limitations of the claims except for the material as claimed. The materials as claimed are well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the materials as claimed into Pacetti et al.'s coating. Doing so would amount to mere substitution of one material for another within the same art that would perform equally well in Pacetti et al.'s coating or device.

To substitute a well known material based on its suitability for the intended use without special functional significance are not patentable, in re Hotchkiss v. Greenwood, 52 USPQ 248.

Note: The limitation "the primer layer polymers being distinct from the drug reservoir layer polymers" encompasses the same polymers being used for the primer layer and drug reservoir layer but two layers are distinct, one layer of polymers on top of the other layer of polymers.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Primary Examiner
Art Unit 3731

February 21, 2006